

REMARKS

This Response is made to the Office Action of January 26, 2007. Claims 1-18 are pending in this application. Applicants have carefully reviewed the arguments presented in the Office Action and respectfully request reconsideration of the claims in view of the remarks presented below.

Claims 1-4, 10-14 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,968,052 to Sullivan et al. ("the Sullivan patent") in view of U.S. Patent No. 5,501,654 to Failla et al. (the "Failla patent") and in further of U. S. Patent No. 6,146,415 to Fitz (the "Fitz patent"). The Examiner has taken the position that the element referred to as the "gear engaging member" 68 located on the pistol grip 46 in the Sullivan patent is the equivalent of a rotatable thumbwheel and that it would have been obvious to one skilled in the art to incorporate the thumbwheel shown in the Failla patent into the stent delivery device disclosed in the Sullivan patent. However, Applicants strongly disagree with the Examiner's position. The device in the Sullivan patent requires the use of a specialized retraction mechanism, which requires the user to apply repetitive motion to the pistol grip 46, to retract the outer sheath 14 proximally from the collapsed stent 18. The Sullivan patent discloses a retraction mechanism including a rack driver having a rack 80 and rack tab 82 that must be repetitively moved back and forth over a rack strip 84 in order to move the rack strip 84 proximally. This rack strip 84 is attached to pull-wires 32 which are, in turn, attached to the outer sheath 14. As the rack strip 84 is retracted proximally by the rack driver, the pull-wires 32 in turn move the other sheath 14 from the stent 18. This rack tab 82 includes a ratcheting pawl 89 which engages ramped spaced stops 86 formed on the rack strip 84. This ratcheting pawl 89 only engages the stops 86 when the pawl 89 moves in a proximal direction. When the pawl 89 is moved in a distal direction, the pawl 89 and stops 86 do not engage.

The Sullivan device thus requires the use of a pistol grip trigger **46** capable of repetitive motion in order to move the rack driver back and forth over the rack strip **84** to retract the rack strip **84**. A back and forth repetitive motion is not the desired motion normally associated with a thumbwheel. Additionally, in the Sullivan device, a trigger spring **62** is needed to provide a biasing force on the pistol grip trigger **46**. The Sullivan patent reads as follows at Col 4, lines 47-50:

As the trigger 46 is squeezed it rotates to its compressed position, and when released the trigger spring forces the trigger to rotate back to its normal position flush with the trigger stop 66.

Without this biasing element, namely, the trigger spring **62**, the trigger **46** would be unable to move back to its normal position. The use of a rotating thumbwheel which drives a movable rack, as disclosed in the Failla patent, would simply not provide the back and forth movement needed to retract the rack strip **84** used in the Sullivan device. Therefore, the gear and rack mechanism disclosed in the Failla patent is quite different from the actuating mechanism disclosed in the Sullivan patent. For these reasons, Applicants maintain that the piston trigger is a different actuating mechanism than a thumbwheel and that by merely replacing the grip trigger **46** of the Sullivan device with a thumbwheel would not create a workable retraction mechanism.

Moreover, the pistol grip trigger **46** used on the Sullivan device requires a much different hand motion on the part of its user. The pistol trigger **46** requires the user to use his/her index and/or middle fingers to move the trigger in its back and forth motion. The user's thumb would not be used. A thumbwheel, on the other hand, allows the user to rotate the mechanism with one's thumb. One does not normally use an index finger or middle finger to rotate a thumbwheel. Therefore, the hand movement and the particular fingers used in both of these types of mechanisms are quite different from each other. For these reasons, the actuating mechanisms of the Sullivan device and Failla device, in this instance,

would not be readably interchangeable as suggested by the Examiner. Additionally, as pointed out in Applicants' previously filed Amendment, the actuating mechanism in the Failla patent does not move an outer sheath **14** since the outer sheath **14** is affixed to the handle **12**. In the Failla patent, the actuating mechanism actually moves an inner rod **18**. In the Sullivan device, the inner member remains stationary. Therefore, there is an obvious incongruity in combining these patents together as suggested by the Examiner. Accordingly, for at least the numerous reasons stated above, the combination of the Sullivan patent with the Failla patent fails to achieve the basic structure recited in the pending claims. Applicants respectfully request the Examiner to withdraw the obviousness rejection.

Claims 5 and 6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Sullivan patent in view of the Failla patent and in further of the Fitz patent. As addressed above, the combination of the Sullivan patent and the Failla patent fails to achieve the basic structure of the actuating mechanism which is also recited in claim 5. The Fitz patent does not provide any teachings which bear on the failure of the Sullivan/Failla combination to achieve the basic structure recited in these claims. Accordingly, for at least this reason, the combination of the Sullivan, Failla and Fitz patents fails to achieve the structure recited in claims 5 and 6. Applicants respectfully request that the rejection of claims 5 and 6 under 35 U.S.C. 103(a) be withdrawn.

Claims 7 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Sullivan patent in view of the Failla and Fitz patents and in further view of U.S. Patent No. 6,183,443 to Kratoska et al (the "Kratoska patent"). As addressed above, the combination of the Sullivan patent and the Failla patent fails to achieve the basic structure recited in claim 5. The Kratoska patent does not provide any teachings which addresses the failure of the Sullivan/Failla combination to achieve the basic structure recited in these claims.

Additionally, the Examiner has taken the position that an introducer constitutes an outer sheath. However, an introducer, as disclosed in either the Sullivan or Kratoska patents, is not an outer sheath as recited in the claims since an introducer is not designed to prevent the distal end of the inner catheter member from moving distally when the outer restraining member is being retracted via the control handle. Rather, an introducer is merely a short conduit used to place the delivery system in a body vessel of the patient. As such, the Sullivan and Kratoska patents fail to disclose an outer sheath in accordance with the present invention. In view of these arguments, Applicants request that the rejections under 35 U.S.C. 103(a) be withdrawn.

Claims 8 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Sullivan patent in view of the Failla and Fitz patents and in further view of U.S. Patent No. 4,624,243 to Lowery et al (the "Lowery patent"). Again, as addressed above, the combination of the Sullivan patent and the Failla patent fails to achieve the basic structure recited in claim 5. For this reason alone, claims 8 and 9 are patentably distinct from the cited art. Applicants again note that the Sullivan patent fails to disclose an outer sheath which is attachable to the entry point of the patient to provide a conduit for the delivery catheter to prevent the distal end of the inner catheter member from moving distally. The metal introducer disclosed in the Lowery is not an outer sheath in accordance with the present invention for the same reasons. Therefore, the combination of the Lowery patent with these three other patents fails to achieve the structure recited in claims 8 and 9. Applicants again respectfully request that the rejections under 35 U.S.C. 103(a) be withdrawn.

It is respectively urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Please charge any fees payable in connection with this response to Deposit Account No. 06-2425.

Respectfully submitted,

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